MIND THE GAP

The Real Impact of Quality Gaps on Medical Device Companies

Medical device quality leaders commonly weigh the impact of quality lapses individually as they occur, but often lack a complete picture of their collective costs, effect on audits, and quality subsystem root causes.

QUALITY GAPS TAKE A HEAVY TOLL

$26B–$36B
Annual direct cost of poor quality in the medical device industry[1]

$1B–$3B
Indirect quality failure cost potential for a single medium to large medical device company[1]

Medical device manufacturers are hit by both direct and indirect costs stemming from quality issues. Aside from lost revenue, companies may experience market-cap declines, customer satisfaction issues, serious legal consequences, and business closure.

QUALITY GAPS EXACERBATE AUDIT CONCERNS

2,235
Total FDA medical device quality system inspections in 2017[2]

49%
Percentage of inspection outcomes that concluded a need for quality actions[2]

Nearly half of 2017 FDA inspections found gaps in quality system management that called for "voluntary" or "official" actions. Responding to FDA and other inspections requires controlled and traceable records throughout the new product introduction process.

QUALITY GAPS STEM FROM SUBSYSTEM FAILURES

#1 and #2
Total FDA medical device quality system inspections in 2017[2]

360
Number of 2017 Form 483 observations centered on document control[2]

Inadequate CAPA procedures per 21 CFR 820 resulting in high numbers of warning letters. Document control deficiencies spanned DMRs, DHFs, and insufficient revision control processes.

TOP-PERFORMING COMPANIES...

1. Manage product design and quality processes in a single system.
2. Foster a collaborative culture to mitigate failures fast and effectively.
3. Track product and quality process analytics to fast-track approvals for 510(k) and PMA.

COMPLIANT COMPANIES...

1. Begin, continue, and end with a plan. The Design Control Plan should ensure all audit requirements can be met.
2. Reduce risks with increased visibility and real-time collaboration for internal teams and external partners.
3. Manage design controls in context with product design to meet requirements and deliver safe devices.

THRIVING COMPANIES...

1. Adopt a product-centric QMS methodology to ensure complete control and traceability between design and quality processes.
2. Ensure that all key stakeholders have immediate access to collaborate and speed CAPA resolution.
3. Provide control of DHF, DMR, SOPs, in context with the entire product record to reduce quality blind spots and failures.

Close Your Quality Gaps

Quality system failures vary, but a common problem stems from having separate system and team silos. The best way to avoid quality failures is to leverage a single system for all impacted teams.

Get our free eBook to see how Arena's unique product-centric QMS solution closes quality gaps by giving quality, engineering, operations, and supply chain teams better visibility and traceability throughout the new product development and introduction (NPDI) process.

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SOURCES

[1] https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/capturing-the-value-of-good-quality-in-medical-devices

[2] https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/UCM597261.pdf